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CASE



FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV722485543US

Express Mail Label Number

November 30, 2005

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT OF

GREIL ET AL.

U.S. PATENT NO: 6,979,641

ISSUED: SEPTEMBER 27, 2005

FOR: CRYSTALLINE  $\beta$ -LACTAM INTERMEDIATE

Certificate  
DEC 06 2005  
of Correction

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Request for Certificate of Correction under CFR § 1.322

Sir:

Pursuant to 37 CFR 1.322, it is hereby respectfully requested that a Certificate of Correction be issued for United States Patent 6,979,641 containing the corrections set forth on the appended Form PTO 1050.

Each of the errors is believed to be attributable to the Patent and Trademark Office as is evident from the following table:

<u>Location and/or Error in Printed Patent</u>	<u>Location of Support in Specification or Amendment</u>
Title Page, Abstract, line 4, insert "carbonyloxy)ethyl ester is provided as an intermediate in the production and remove the "/" in between "isopropoxy/crystallization"	Amendment, dated June 4, 2003, page 1

Attached is a duplicate of Form PTO 1050, with at least one copy being suitable for printing.

Since the above errors are not ascribable to the patentees, no fee is believed to be necessitated by this Request for Certificate of Correction. However, in the event that a fee is

DEC 6 2005

required, the Commissioner is hereby authorized to charge said fee to Deposit Account No. 19-0134 in the name of Novartis.

Please send the Certificate of Correction to the address currently associated with Customer No. 001095, viz:

Novartis  
Corporate Intellectual Property  
One Health Plaza, 104/3  
East Hanover, New Jersey 07936-1080


Respectfully submitted,

Novartis  
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Encls.: Form PTO 1050 (2)  
Postcard

JDT:alg

Date:

*11/30/05*

  
\_\_\_\_\_  
John D. Thallemer  
Attorney for Patentee  
Reg. No. 34,940

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO : 6,979,641  
DATED: : September 27, 2005  
INVENTOR(S) : GREIL ET AL.

It is certified that there is/are an error(s) in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

The Abstract, should read as follows:

-- The novel intermediate compound crystalline 7-[2-(2-formylaminothiazol-4-yl)-2-(Z)-(methoxyimino)acetamido]-3-methoxymethyl-3-cephem-4-carboxylic acid-1-(isopropoxycarbonyloxy)ethyl ester is provided as an intermediate in the production and crystallization of cefpodoxime proxetil. The crystallization process comprises dissolving or suspending the intermediate in the presence of a nitrile or a ketone or mixtures thereof; at a ratio of 1 gm of the intermediate to 2-15 ml nitrile; or at a ratio of 1 gm of the intermediate to 3-15 ml ketone; in the presence of 50-80 ml water; and thereafter isolating the intermediate in crystalline form and converting the intermediate by splitting off the formyl group from the amino group attached to the thiazolyl group, to obtain the desired product cefpodoxime proxetil, in the form of a diastereoisomeric mixture in a ratio of B/(A+B) of 0.5 to 0.6. --.

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PATENT NO. 6,979,641

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO : 6,979,641  
DATED: : September 27, 2005  
INVENTOR(S) : GREIL ET AL.

It is certified that there is/are an error(s) in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

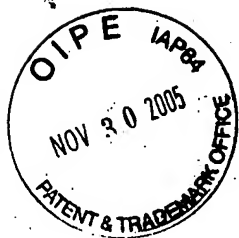
The Abstract, should read as follows:

-- The novel intermediate compound crystalline 7-[2-(2-formylaminothiazol-4-yl)-2-(Z)-(methoxyimino)acetamido]-3-methoxymethyl-3-cephem-4-carboxylic acid-1-(isopropoxycarbonyloxy)ethyl ester is provided as an intermediate in the production and crystallization of cefpodoxime proxetil. The crystallization process comprises dissolving or suspending the intermediate in the presence of a nitrile or a ketone or mixtures thereof; at a ratio of 1 gm of the intermediate to 2-15 ml nitrile; or at a ratio of 1 gm of the intermediate to 3-15 ml ketone; in the presence of 50-80 ml water; and thereafter isolating the intermediate in crystalline form and converting the intermediate by splitting off the formyl group from the amino group attached to the thiazolyl group, to obtain the desired product cefpodoxime proxetil, in the form of a diastereoisomeric mixture in a ratio of B/(A+B) of 0.5 to 0.6. --.

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PATENT NO. 6,979,641



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6/4/2003  
Date of Deposit

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1619

GRIEL ET AL.

APPLICATION NO: 10/001,544

FILED: OCTOBER 31, 2001

FOR: CRYSTALLINE BETA-LACTAM INTERMEDIATE

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

A

AMENDMENT

Sir:

In response to the Office Action dated March 5, 2003, response to which is due June 5, 2003, entry of the following amendment is respectfully requested.

IN THE SPECIFICATION

✓ Delete the Abstract, page 18, and substitute therefore the following abstract.

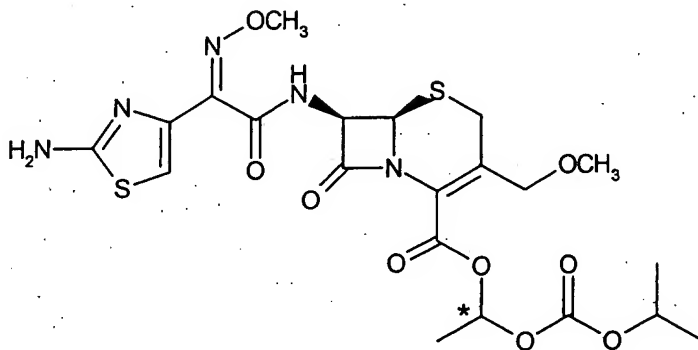
**Abstract**

The novel intermediate compound crystalline 7-[2-(2-formylaminothiazol-4-yl)-2-(Z)-(methoxyimino)acetamido]-3-methoxymethyl-3-cephem-4-carboxylic acid-1-(isopropoxycarbonyloxy)ethyl ester is provided as an intermediate in the production and crystallization of cefpodoxime proxetil. The crystallization process comprises dissolving or suspending the intermediate in the presence of a nitrile or a ketone or mixtures thereof; at a ratio of 1 gm of the intermediate to 2-15 ml nitrile; or at a ratio of 1 gm of the intermediate to 3-15 ml ketone; in the presence of 5-80 ml water; and thereafter isolating the intermediate in crystalline form and converting the intermediate by splitting off the formyl group from the amino group attached to the thiazolyl group, to obtain the desired product cefpodoxime proxetil, in the form of a diastereoisomeric mixture in a ratio of B/(A+B) of 0.5 to 0.6.

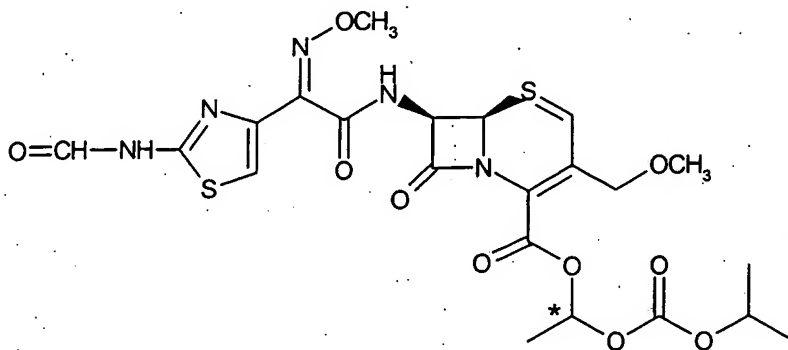
## IN THE CLAIMS

- ✓ Delete Claims 3-11.
- ✓ Add the following claims 14-19.

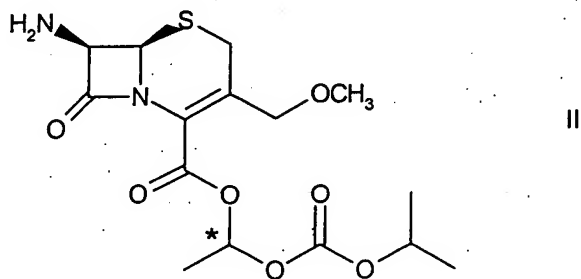
14. A process for the production of a mixture of diastereoisomers of cefpodoxime proxetil of formula



in a diastereoisomeric ratio B/(A+B), wherein B is the more apolar of the two diastereoisomers, of 0.5 to 0.6, the diastereoisomers being with respect with the carbon atom marked with a star in formula II, comprising producing a mixture of diastereoisomers of a compound of formula



by acylating a compound of formula



with activated Z-(2-formamidothiazol-4-yl)-methoxyimino acetic acid, removing solvent from the reaction mixture obtained;

and crystallizing a compound of formula I in the residue obtained;

by dissolving or suspending the compound of Formula I in the presence of a nitrile or a ketone or mixtures thereof;

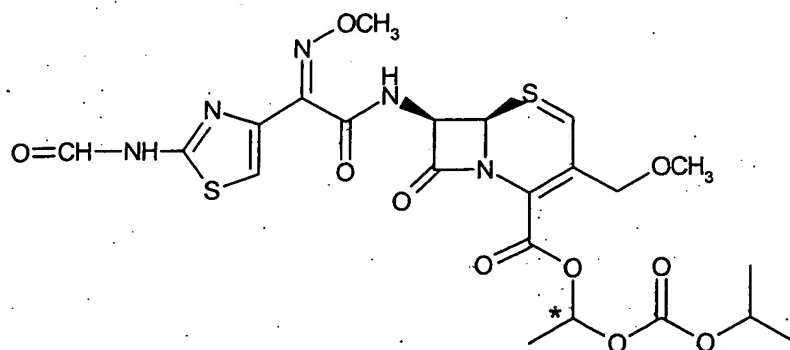
at a ratio of 1 gm of the compound of Formula I to 2-15 ml nitrile; or at a ratio of 1 gm of the compound of Formula I to 3-15 ml ketone; in the presence of 5-80 ml water;

and thereafter isolating the compound of formula I in crystalline form and converting the compound of formula I by splitting off the formyl group from the amino group attached to the thiazolyl group, to obtain a compound of formula II, in the form of a diastereoisomeric mixture in a ratio of B/(A+B) of 0.5 to 0.6.

15. A process according to Claim 14 wherein the nitrile is acetonitrile.

16. A process according to Claim 14 wherein the ketone is acetone.

17. A process for the production of a compound of formula I in crystalline form



comprising dissolving or suspending the compound of Formula I in the presence of a nitrile or a ketone or mixtures thereof;

at a ratio of 1 gm of the compound of Formula I to 2-15 ml nitrile; or at a ratio of 1 gm of the compound of Formula I to 3-15 ml ketone; in the presence of 5-80 ml water;

and thereafter isolating the compound of formula I in crystalline form.

18. A process according to Claim 17 wherein the nitrile is acetonitrile.

19. A process according to Claim 17 wherein the ketone is acetone.

REMARKS

The Claims in the case are Claims 1, 2, 12, and 14-19. Claims 1, 2, and 12 have been allowed.

Claims 14-19 are rewritten versions of the process claims 3-11. Claims 14, 15 and 16 generally correspond to Claims 8, 10 and 11. Claims 17, 18, and 19 generally correspond to Claims 3, 10, and 11.

The Claims have been rewritten to avoid the rejection of the Claims under Section 112, both 1<sup>st</sup> and 2<sup>nd</sup> paragraphs. The claims particularly point out and distinctly claim the subject matter pertaining to the key step of the crystallization. Support for the amounts of the solvents is found in the specification at p. 5, lines 10-27, as well as the Examples.

Claims 5 and 7 have been cancelled, and the rejection of those claims is moot. The use of the term "e.g." is absent from the claims now present in the case. There is no improper dependency of newly added claims.

The abstract has been rewritten to provide a more complete statement.

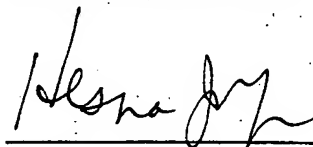
Should the Office feel that telephonic communication with Applicants' representative would further the prosecution of the instant application, the examiner is invited to telephone the undersigned.

Early and favorable action on the merits is earnestly solicited.

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One Health Plaza, Building 430  
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30950amend

Date: June 4, 2003

Respectfully submitted,



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